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General Counsel

September 5, 2002

Dockets Management Branch
Food & Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

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Re: Docket No. 02N-0209; First Amendment Issues

The Animal Health Institute (AHI) is the national trade association representing manufacturers of animal health products -- the pharmaceuticals, vaccines and feed additives used in modern food production, and the medicines that keep livestock and pets healthy. Our member companies produce the vast majority of all such products sold in the United States, as well as serving a significant segment of the world market.

AHI supports the FDA's introspection and analysis of its regulations and policies in light of the First Amendment's protections afforded commercial free speech. In support of this process, we offer the following comments.

Promotion of Extra-Label Uses

"[I]t is undisputed that the prescription of drugs for unapproved uses is commonplace in modern medical practice and ubiquitous in certain specialties." *Washington Legal Foundation v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000). Although this statement addressed human medical practice, it is true to an even larger degree with veterinary uses of drugs. The ability of veterinarians to obtain, use and prescribe drugs for uses or at dosages that are not approved on the label are critical to the ability of the veterinarian to treat and prevent disease. The right of the veterinarian to use drugs in an extra-label fashion was explicitly condoned in the Animal Medicinal Drug Use Clarification Act of 1994, P.L. 103-396, October 22, 1994.

We recognize the competing public interests of veterinarians and producers having access to legitimate information about extra-label drug uses versus having supplemental applications filed to gain approval for new indications. In partnership with the industry, producer groups and the veterinary profession, we believe FDA should explore and allow additional mechanisms by which the manufacturer can disseminate truthful, non-misleading information about extra-label uses. We urge FDA to look at the realities of the differing constituencies that use FDA regulated products when FDA reconsiders regulating commercial speech regarding extra-label uses. Markets for veterinary drugs are relatively small, and the cost

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of obtaining approvals is relatively high. This means that although there may be many appropriate and medically sound extra-label uses of a veterinary drug, it often does not make economic sense for the manufacturer to spend millions to supplement the approved labeling of a product. Therefore, the public is hurt if the veterinarian and producer are unaware of legitimate extra-label uses.

Food Labeling

The public has the right to receive truthful, non-misleading food labeling and promotional information regarding food. Such information facilitates consumer choice. However, food labeling and promotional materials occasionally claim or imply that a food is better, healthier or safer because it was produced without the use of a particular veterinary drug product. Such labeling and promotion is untruthful and misleading, as the FDA has made a determination that these products are safe and effective. Moreover, FDA has specifically addressed the safety of the food derived from animals treated with such products during the review that led to their approval. In reviewing its policies and regulations regarding food labeling and promotion, FDA should ensure that this type of untruthful and misleading activity does not persist.

An example of such untruthful and misleading labeling and promotional materials is found in the dairy industry regarding the protein-based product recombinant bovine somatotropin (rBST). rBST is an approved new animal drug found to be safe and effective by FDA. FDA has determined that milk from cows supplemented with rBST is no different than milk from non-supplemented cows. In the Federal Register, FDA has made it clear that labels and promotional materials implying that milk from non-rBST supplemented animals is safer or of higher quality than milk from rBST supplemented cows would be misleading. *See* 59 Fed. Reg. 6280 (1994). Yet, numerous examples of violative labeling exist. There are milk and dairy labels that state the product was "produced without the use of hormones," which is impossible since no milk is created without the hormones causing the cow to lactate. Some state that, "No hormones are added" followed by the statement that they add vitamin D₃, a hormone. Other labels state, "when it comes to your health, we insist that dairies ... do not use rBST." This is exactly what the FDA has indicated would be misleading to consumers, and they are but a few examples. Additionally, we have attached research conducted by SWR Worldwide for Citizens for the Integrity of Science. The research, conducted in New York and New Jersey found that a majority of consumers are being misled by such labels.

Consumers have the right and should have the ability to choose the food they purchase based on truthful, non-misleading labels and promotional material. Labeling or promotional material that is untruthful or misleads based on misrepresented science may be used to dissuade consumers from buying competing products because they are perceived to be unsafe or to cause other adverse consequences. They cause consumers to misperceive the actual characteristics of the food. This actually impedes the consumer's ability to make an informed choice. Deceptive labeling is also unfair to those food companies who are properly labeling their products because

they are sometimes being put at a competitive disadvantage by those who are misleading the consuming public.

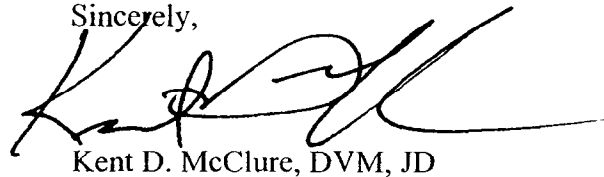
Therefore, FDA should actively enforce food labeling law and regulation requiring that labels and promotional material contain only truthful and non-misleading statements. If this is accomplished via a label disclaimer, the disclaimer should be as prominent as and physically alongside any claims. The attached consumer data shows, with the example of milk labels, that where disclaimers are employed (and many do not use them), they are not noticed by consumers due to their presentation.

Dietary Supplements

FDA has taken the position that the Dietary Supplement Health and Education Act of 1994 (DSHEA) does not apply to dietary supplements for animal use. We support this interpretation by FDA. We are concerned about the quality, safety, and efficacy of dietary supplement products for veterinary use. We believe that many of the claims made by dietary supplements for animals are not backed by valid scientific data.

Despite this interpretation by FDA that DSHEA does not apply to dietary supplements for animals, we observe instances where such products make claims of disease prevention, treatment or production enhancement, with or without the DSHEA disclaimer in small print. However, it is important that consumers understand and differentiate between new animal drugs that have demonstrated safety and efficacy (or scientifically valid extra-label uses) versus dietary supplements that have not. FDA should treat any dietary supplements for animals that make claims for disease prevention, cure, mitigation, or treatment or any claims for enhancing production of food animals as new animal drugs that must demonstrate safety and efficacy. Where a dietary supplement for animals asserts disease or production related claims, there is no justification to afford commercial speech regarding them a lesser standard regarding whether the information is truthful or misleading than to new animal drugs.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kent D. McClure', with a long horizontal flourish extending to the right.

Kent D. McClure, DVM, JD

Report on
Perceptions of Milk Labels in the
Southern District of New York

December 4, 2001



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1. Introduction and Methodology

A non-profit conservation and natural resource advocacy group commissioned SWR Worldwide to conduct a research study among milk consumers in the Southern District of New York to understand perceptions regarding statements and claims made on milk cartons. Four hundred (n=400) intercept interviews were conducted between October 29 and November 29, 2001, with men (43% of sample) and women (57% of sample) over the age of 18 who were shopping in one of three facilities in New York State:

- The Galleria at White Plains (n=131)
- Bay Plaza Shopping Center (The Bronx) (n=134)
- The Poughkeepsie Galleria (n=135)

In order to participate in the study, consumers were required to pass an initial screener to ensure that (1) they were the primary purchasers of milk in their household; and (2) they lived in the Southern New York District. Those who completed the screening procedure were offered an incentive (ranging from \$2.00 to \$5.00) and asked to participate in a 5 to 7 minute interview.

Each interview was conducted in a market research facility within the shopping complex where each professional interviewer was trained in methodology and technique by a member of SWR Worldwide's professional staff. The instructions given to each interviewer can be found in the appendix.

At the beginning of each interview, respondents were shown two containers (cartons) of milk and asked a series of questions. Half way through the interview, respondents were asked a second series of questions based on two additional containers of milk.

One of the containers in each series was a "control container." The other two containers that were the focus of the research were: Farmland 1% (one quart) and Trader Joe's 2% (half gallon).

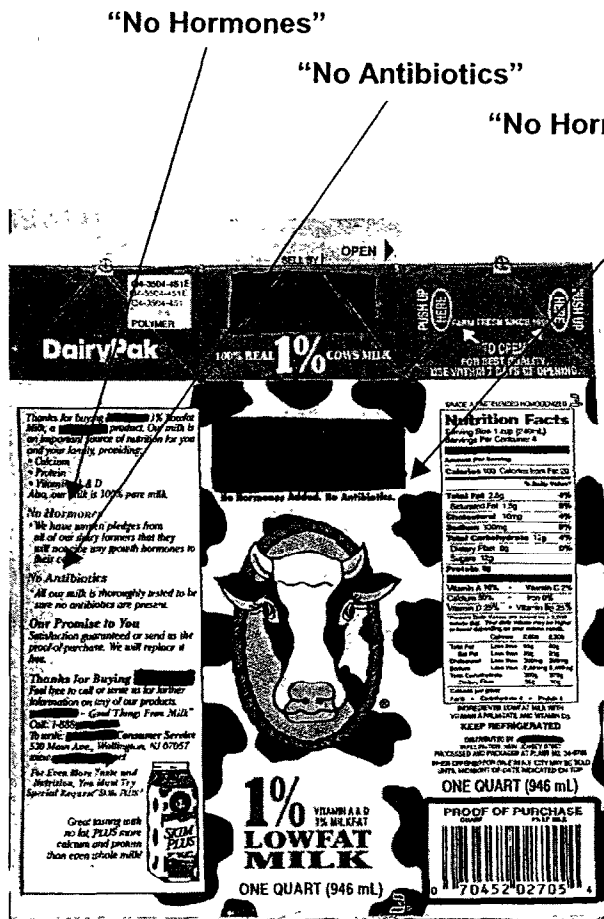
The Farmland 1% carton included a statement on the front that read, "No Hormones Added. No Antibiotics." Two other statements regarding "No Hormones" and "No Antibiotics" were also printed on the side of the container.

The Trader Joe's 2% container included a statement found on the front label that read "THIS MILK DOES NOT CONTAIN THE GROWTH HORMONE rBST."

Each of the control containers included the exact same size and fat content as the Farmland and Trader Joe's containers they were matched with. Additionally, the control cartons did not include any language regarding statements or claims about the milk beyond the nutritional information.

The interviewers rotated which pair of containers each respondent saw first.

Series 1



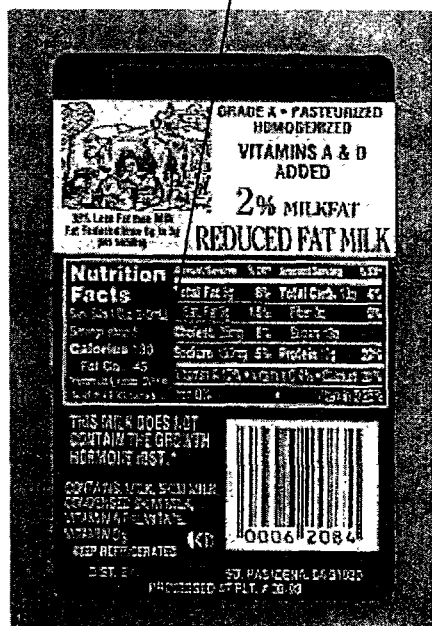
Farmland 1% ("blue")



control 1% ("purple")

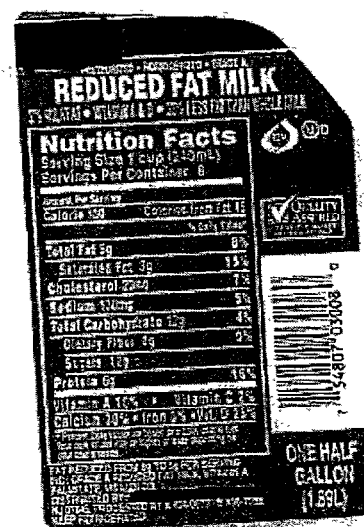
Series 2

"THIS MILK DOES NOT
CONTAIN THE GROWTH
HORMONE rBST."



Trader Joe's 2% ("green")

OCT 10 EXCEPT NYC
BY B OCT 08



control 2% ("yellow")

After each respondent was shown a pair of milk cartons, one test, and one control, the respondents were asked if he or she noticed a difference – and to describe all of the differences they noticed.

The interviewer then directed the respondent's attention to specific language on the test carton stating that the milk had "No Hormones Added. No Antibiotics" in the case of the Farmland carton test or "THIS MILK DOES NOT CONTAIN THE GROWTH HORMONE rBST" in the case of the Trader Joe's container test. After pointing out the statement, each respondent was asked, which milk (between the test and the control), if either was better.

After these questions, respondents were asked two other questions – one was about a statement on the Trader Joe's cap and about some information about milk production.

The complete results of the study follow.

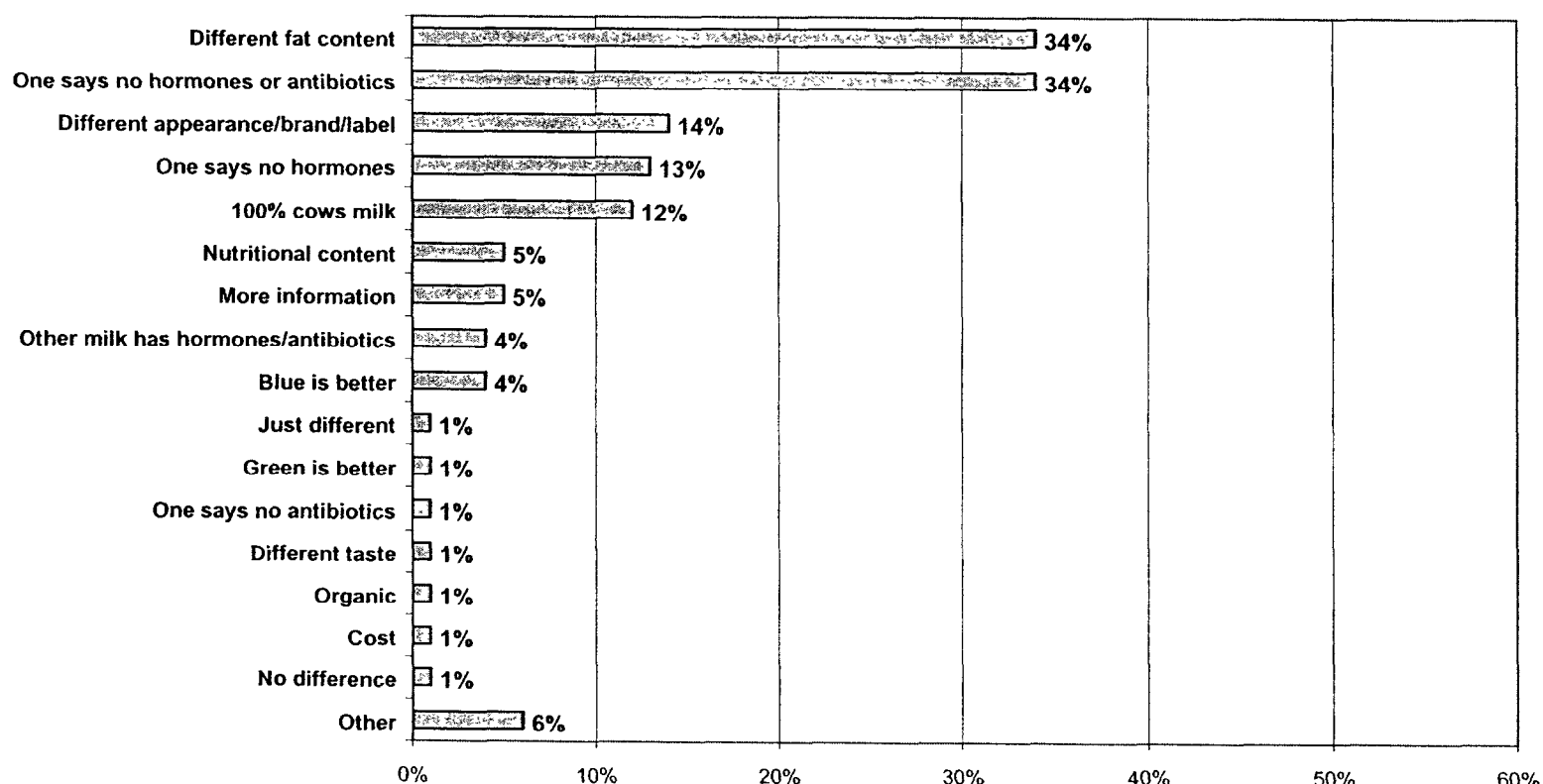
2. Farmland 1% Milk

The Farmland 1% milk was shown in a carton and compared to a similar-sized carton of Tuscan 1% milk. The cartons were labeled “Blue” for Farmland and “Purple” for Tuscan, the control carton. All references to the brand were blacked out, and respondents used the color labels to differentiate.

Forty-two percent (42%) of respondents reported that there was a difference between the milk contained in the two cartons. Of those who believed there was a difference, more than a majority (52%) reported that the difference was related to statements regarding hormones or antibiotics.

Nearly half (48%) mentioned that the Farmland milk either had “no hormones,” “no antibiotics,” or both; whereas an additional four percent (4%) stated that the difference was that Tuscan milk did have hormones or antibiotics.

“Can you please tell me specifically all of the differences you think there are between the milk contained in the two cartons?” (Sample= “Yes” in Q1) (n=168)



In the next two questions, the interviewer pointed to the “No Hormones” and “No Antibiotics” statements on the side of the Farmland carton. After seeing the “No Hormones” statement (with the description of the Farmland farmer pledge), 58 percent of all respondents said that they believed the Farmland milk to be better. Thirteen percent (13%) said that the Tuscan milk was better, 24 percent said they were the same and 5 percent did not know.

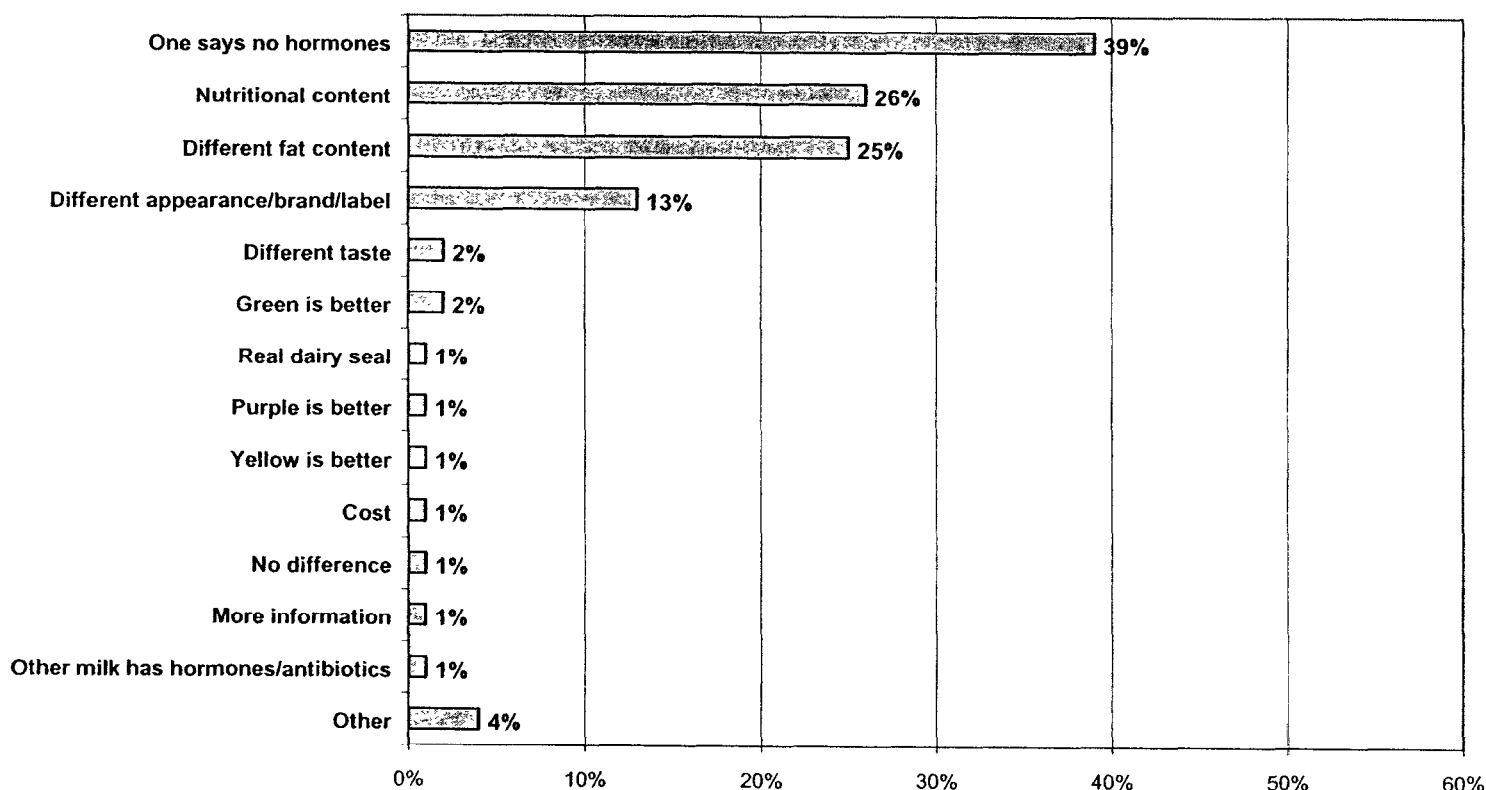
In response to the “No Antibiotics” statement on the side of the container, 60 percent of all respondents reported that the Farmland milk was better. Ten percent (10%) said that the Tuscan milk was better, 24 percent said they were the same, and 6 percent did not know.

3. Trader Joe's 2% Milk

Fewer respondents noticed a difference between the Trader Joe's 2% milk and the America's Choice 2% milk. Among the 35 percent that saw a difference, 39 percent said that one of the milks had no hormones.

The following chart represents all of the answers given.

"Can you please tell me specifically all of the differences you think there are between the milk contained in the two cartons?" (Sample="Yes" to Q5) (n=140)



In the next question, the interviewer directed the respondent to the statement on the Trader Joe's label that says, "This milk does not contain the growth hormone rBST," and asked if based on that statement, the respondent thought either milk was better. Out of all of the respondents, 54 percent thought that the Trader Joe's milk was better. Seventeen percent thought the America's Choice was better, 25 percent thought they were both the same, and 4 percent did not know.

4. The FDA Statement

In an unaided exercise, only 7 percent of respondents recalled noticing the FDA Statement on the Trader Joe's container cap that read: No significant difference has been shown between milk derived from cows treated with artificial hormones and those not treated with artificial hormones.



Caps shown to respondents did not have price sticker.

Next, all respondents were shown the same statement typed on an index card and shown where the statement appeared on the container cap. After reviewing the statement on the card, nearly two-thirds of all consumers (65%) in the survey reported that they found this statement helpful to them as a milk consumer.

5. Milk Production

At the end of the survey, respondents were read the following four statements describing milk production.

- All milk has hormones, as they are a required component of natural milk production;
- No dairy adds hormones to milk;
- No dairy adds pesticides to milk;
- No milk from cows ever treated with antibiotics is ever sold to the public.

Respondents were then asked if they were provided with this information – if they believed statements on milk labels such as hormone-free, pesticide-free and antibiotic free to be misleading, or not.

More than two out of five consumers (42%) believed that these statements were misleading.